IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

DEBRA DIAMOND,	)	CASE NO. 1:13-CV-2481
	)	
Plaintiff,	)	JUDGE OLIVER
	)	
v.	)	MAGISTRATE JUDGE VECCHIARELLI
	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
	)	
Defendant.	)	**REPORT AND RECOMMENDATION**

Plaintiffs, Debra and Ronald Diamond ("Plaintiffs"), challenge the final decision of Defendant, the Secretary of Health and Human Services ("Secretary"), denying Ms. Diamond coverage, under her Medicare Part D voluntary prescription drug program, for medication prescribed by her physician. This Court has jurisdiction to review the final decision of the Secretary pursuant to § 1860D-4(h)(1) of the Medicare Act, 42 U.S.C. § 1395w-104(h)(1) ("Act"). This case is before the undersigned United States Magistrate Judge on referral for the issuance of a Report and Recommendation. (*See* Dkt. entry at 06/03/2014.) For the reasons set forth below, the Magistrate Judge recommends that: (1) the claims of Mr. Diamond be DIMISSED for lack of jurisdiction; and (2) the Secretary's final decision be AFFIRMED.

I. PROCEDURAL HISTORY

A. Prescription and Initial Denials of Coverage by the Insurance Company

Mrs. Diamond is enrolled in a voluntary prescription drug program, commonly referred to as a Medicare Part D program, offered by United Healthcare Insurance

Company ("United Healthcare"). (Administrative Transcript ("Tr.") 8.)[1] Her physician, James Bressi, D.O., prescribed Mrs. Diamond oral transmucosal fentanyl citrate ("OTFC"), which has the brand name Actiq,[2] to treat the pain associated with her oculopharyngeal muscular dystrophy ("OPMD").[3] (*Id*.) In February 2013, United Healthcare refused to cover the cost of the OTFC on the basis that the medication was not approved by the Food and Drug Administration ("FDA") to treat Mrs. Diamond's condition. (Tr. 894, 921.) Thereafter, Dr. Bressi sought a redetermination of coverage. (Tr. 912.) On March 1, 2013, United Healthcare confirmed its denial of coverage on the basis that: (1) OTFC was not approved by the FDA to treat non-cancer pain; and (2) the off-label use of OTFC to treat OPMD did not meet criteria set forth in relevant pharmacological compendia. (*Id*.)

---

[1] The Administrative Transcript contains numerous documents that bear page numbers individual to each document. The Administrative Transcript also bears small numbers in the bottom right hand corner of each page. These numbers, however, do not correspond to the page numbers assigned by this Court's electronic filing system ("ECF"). The Secretary cites to the page numbers assigned by ECF. Plaintiffs do not refer to the record in their brief. For ease of reference, this Report and Recommendation cites to the page numbers assigned by ECF.

[2] Actiq is an oral lozenge that contains the pain medication fentanyl. *See* Food and Drug Administration Actiq Medication Guide, available at http://www.fda.gov/downloads/Drugs/DrugSafety/UCM085817.pdf (last visited Dec. 30, 2014.)

[3] OPMD is a form of muscular dystrophy, a degenerative disease that affects the voluntary muscles; the disease is named for the muscles it affects first, i.e., the eyelids and throat. *See* Muscular Dystrophy Association, Overview, Oculopharyngeal Muscular Dystrophy, available at http://mda.org/disease/oculopharyngeal-muscular-dystrophy/overview (last visited Dec. 30, 2014.)

B. Administrative Review

1. Independent Review Entity

On March 5, 2013, Mrs. Diamond, through Dr. Bressi, sought review of United Healthcare's decision by an independent review entity ("IRE") tasked with reconsidering Medicare Part D coverage denials. (Tr. 904-05.) Dr. Bressi argued that Mrs. Diamond required OTFC to control the pain resulting from her OPMD because she was allergic to fentanyl pain patches and was unable to swallow tablets as a result of her condition. (Tr. 905.) Dr. Bressi also indicated that, when Mrs. Diamond enrolled in her United Healthcare plan, a representative of United Healthcare told Plaintiffs that Actiq was covered. (*Id*.) On March 15, 2013, the IRE issued a decision upholding United Healthcare's denial of coverage for the OTFC, on the basis that Dr. Bressi had not prescribed the medication for a "medically accepted indication." (Tr. 839-40.)

2. Administrative Law Judge

In April 2013, Mrs. Diamond, through counsel, requested review of the IRE's decision by an administrative law judge ("ALJ"). (Tr. 837-38.) On May 13, 2013, after a hearing, an ALJ determined that United Healthcare was required to cover the cost of the OTFC. (Tr. 715-36.) The ALJ provided the following reasons:

> I. When [Plaintiffs] spoke with a United Healthcare sales representative about enrolling in its Medicare Part D Prescription Drug Plan, the sales representative told them that the plan covered Actiq, and they enrolled in the plan in reliance on this representative [*sic*] by the sales representative. After they enrolled, they learned the plan did not cover Actiq when [Plaintiff'] claim was denied.

> II. [Mrs. Diamond] is one of only five people in the US with a variant of OPMD that causes severe pain. The rarity of this disease makes it very difficult to impossible to find enough patients to do clinical trials, so there is insufficient peer-reviewed medical literature in existence to support the treatment of this disease as a "medically accepted indication" for Actiq. Due to the lack of evidence of the treatment of OPMD with Actiq, OPMD must be treated as a medically accepted indication for Actiq.
>
> III. Based on the evidence, Actiq is medically and reasonably necessary to treat [Mrs. Diamond's] OPMD.

(Tr. 734.)

3. Medicare Appeals Council

On July 8, 2013, the IRE sought review of the ALJ's decision by the Medicare Appeals Council ("Appeals Council"), arguing that the ALJ made a material legal error. (Tr. 65-79.) In support of its request for review, the IRE included: (1) the FDA labeling information for Actiq (tr. 148-204); and (2) relevant sections of DRUGDEX and the American Hospital Formulary Service Drug Information ("AHFSDI"), two Medicare-approved pharmacological compendia (tr. 205-662; 663-98). The "Indications and Usage" section of the FDA label for Actiq provided as follows:

> ACTIQ is an opioid agonist indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

(Tr. 148.) Neither of the medical compendia included any citation to support the use of Actiq to treat any pain other than breakthrough cancer pain for patients who have

developed a tolerance to other forms of pain management.[4]

On September 6, 2013, the Appeals Council reversed the decision of the ALJ and determined that United Healthcare was not required to cover the cost of the OTFC. (Tr. 8-18.) The Appeals Council made the following relevant conclusions:

> [T]he Council acknowledges that [Mrs. Diamond] and [the] ALJ have presented compelling arguments that [Mrs. Diamond's] use of OTFC is medically supported by the medical records in this case. The Council does not question that [Mrs. Diamond] has received significant pain relief with OTFC, nor does the Council question her physician's judgment in prescribing OTFC. However, the determinative legal issue is whether the use of OTFC, as prescribed for [Mrs. Diamond], meets the criteria in the Medicare statute and regulations for a medically accepted indication and thus meets the definition of a Part D drug.
>
> As explained below, the Council finds reversible legal error in the ALJ's decision. The ALJ erred by[:] (1) relying upon principles of estoppel, and (2) not applying the regulatory as well as the statutory requirements for whether a drug is being used for a "medically accepted indication."
>
> * * *
>
> The Act and implementing regulations limit the definition of a Part D drug to a prescription drug which has been approved by the FDA for safety and efficacy. The drug must be prescribed for an FDA-labeled indication, or for a use which is supported by a citation included or approved for inclusion in any of the recognized compendia.
>
> * * *
>
> There is no question that [Mrs. Diamond's] use of OTFC in this case is not FDA approved (*i.e.*, not "on label"). Therefore, [her] "off-label" use of OTFC must be supported

[4] There is no dispute in this case regarding either the contents of the FDA label for Actiq or the lack of a compendium citation supporting the use of Actiq for the treatment of pain associated with OPMD.

> by a statutorily recognized compendium. However, the Council has determined that the use of OTFC for non-cancer pain is not supported by a statutorily recognized compendium. Specifically, as the IRE states, the FDA label and the Medicare drug compendia only support the use of OTFC to treat cancer-related pain. There is no off-label use indicated in any of the approved compendia for use of OTFC for treatment of chronic pain associated with her rare variant of OPMD. For these reasons, the Council disagrees with the ALJ's analysis and conclusion. OTFC, in this instance, was not prescribed for a "medically accepted indication," and, therefore, does not meet the legal definition of a Part D drug.

(Tr. 15-18.) The Council's decision constitutes the Secretary's final decision in this case. *See* 42 C.F.R. § 423.2130.

C. Proceedings in this Court

On November 7, 2013, Plaintiffs filed their Complaint challenging the Secretary's final decision, and requesting that this Court reverse the decision of the Council. (Doc. No. 1.) The parties have completed briefing in this matter. (Doc. Nos. 15, 16.) Plaintiffs assert the following as their "Ultimate Issues" in this case:

> 1. Inasmuch as the Defendant Secretary has not challenged the ultimate finding of the [ALJ] that the subject medication is "reasonable and necessary" for treatment of [Mrs. Diamond's] OPMD, the decision of the [ALJ] must stand.
>
> 2. Inasmuch as [Mrs. Diamond] satisfies the two-pronged test of the Medicare Improvements for Patients and Providers ("MIPPA"), the subject medication should be covered under Part D of Medicare.
>
> 3. Where the Defendant Secretary has not instigated any medical research into an appropriate treatment for OPMD, it is not privileged to defend his/her position on the basis that the subject medication does not meet the definition of "medically accepted indication." In the absence of any medical research

> on this subject, one is left to state that a "medically accepted indication" can be satisfied by other tests promulgated in the applicable regulations, such as the two-pronged test of the MIPPA.

(Doc. No. 15 at 2-3.)

II. LAW & ANALYSIS

A. Mr. Diamond's Claims

As a preliminary matter, the Secretary argues that this Court lacks jurisdiction over the claims of Mr. Diamond in this case, because the Act only permits an appeal by the individual whose claim was denied. The Secretary is correct. The Act limits the ability to appeal to "only the part D eligible individual." 42 U.S.C. § 1395w-104h(1). There is no indication that the Secretary denied any claim for Part D coverage asserted by Mr. Diamond. In their Complaint, Plaintiffs assert that Mr. Diamond "has had to expend monies to pay for his wife's prescription medication as a result of the denial of Medicare Part D coverage." (Doc. No. 1 at ¶ 6.) Plaintiffs, however, cite to no authority that permits Mr. Diamond to assert his claims in the context of judicial review of the Secretary's final decision. Further, to the extent that Mr. Diamond alleges tort claims against the Secretary arising under the Medicare Act, those claims are precluded. *See* *Livingston Care Ctr. Inc. v. United States*, 934 F.2d 719, 721 (6th Cir. 1991) ("The plain language of [the statute permitting judicial review of the final decision of the Secretary] precludes federal courts from entertaining claims based on the jurisdictional provisions of the Tort Claims Act or the statutory grant of jurisdiction over federal questions if the claims 'arise under' the Medicare Act."). Finally, to the extent that Mr. Diamond asserts tort claims in a different context, he has failed to allege the administrative exhaustion

required by the Federal Tort Claims Act. *See* 28 U.S.C. §§ 1346(b)(1), 2675(a). Accordingly, Mr. Diamond's claims should be dismissed for lack of jurisdiction.

B. Standard of Review

Judicial review of the Secretary's decision is limited to determining whether that decision is supported by substantial evidence and is based on proper legal standards. *Brainard v. Sec'y of Health & Human Servs.*, 889 F.2d 679, 681 (6th Cir. 1989). "Substantial evidence is more than a scintilla of evidence but less than a preponderance and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id*. The scope of a Court's review in this context is "limited to an examination of the record only. [Courts] do not review the evidence *de novo*, make credibility determinations nor weigh the evidence." *Id*.

C. Relevant Statutes

The parties' dispute in this case arises out of whether Mrs. Diamond's OTFC is a "covered part D drug," as that term is defined in the Act, such that United Healthcare is required to cover its cost. The Appeals Council concluded that United Healthcare was not required to cover the cost of Mrs. Diamond's OTFC because her physician had not prescribed the medication for a "medically accepted indication" and, thus, the OTFC was not a "covered part D drug."

The term "medically accepted indication" is one element of the definition of a "covered part D drug." 42 U.S.C. § 1395w-102(e)(1). As relevant to this case, the Act defines "medically accepted indication," as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is

supported by one or more citations included or approved for inclusion in any of" several medical compendia enumerated in the Act, including DRUGDEX and the AHFSDI. 42 U.S.C. § 1395w-102(e)(4) (incorporating the definition of "medically accepted indication" set forth in 42 U.S.C. § 1396r-8(k)(6), quoted). In other words, as relevant to this case, United Healthcare is required to cover the cost of a medication only when that medication is prescribed either: (1) for a use indicated in the medication's FDA label; or (2) for a use supported by the compendia enumerated in the Act.

D. Plaintiffs' Assignments of Error

Plaintiffs raise no challenge to the evidentiary support for the Council's conclusions in this case.[5] Rather, Plaintiffs assert that the Appeals Council failed to rely on the proper legal standards in deciding that OTFC was not a "covered part D drug" in this case. Specifically, Plaintiffs argue that: (1) because the Appeals Council did not disturb the ALJ's conclusion that OTFC was "reasonable and necessary" for the treatment of Mrs. Diamond's OPMD, the ALJ's conclusion "must stand"; (2) Mrs. Diamond satisfies the two-prong test of the MIPPA and, thus, United Healthcare is required to cover the cost of her Actiq; and (3) where, as here, there has been insufficient research into alternative indications for a particular medication, a Part D plan enrollee can satisfy the requirements for coverage using alternative tests, including

[5] Even if Plaintiffs' brief is construed to argue that substantial evidence does not support the Council's conclusion, any such argument would fail. The FDA label for Actiq does not include any indication for the medication other than treating the breakthrough pain of cancer patients who are already receiving opioid therapy. (Tr. 148.) Neither of the compendia included in the record supports the use of OTFC for the treatment of pain associated with OPMD. Plaintiff does not refer to any other compendium that supports such a use. Accordingly, substantial evidence in the record supports the Council's conclusion.

the two-prong test in the MIPPA.

1. Reasonable and Necessary

In their first argument, Plaintiffs contend that, because the ALJ concluded that Actiq was "reasonable and necessary" to treat Mrs. Diamond's pain, the Appeals Council erred in determining that the Actiq was not a covered medication.[6] This argument lacks merit. The relevant statutes create two requirements for medication coverage under part D. The first is a general one: Congress has prohibited payment under part D for "any expense incurred for items or services [that] are not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member." *See* 42 U.S.C. § 1395w-102(e)(3) (incorporating the reasonable and necessary requirement of 42 U.S.C. § 1395y(a), quoted). The second, discussed at length above, requires that the medication be prescribed for a "medically accepted indication." 42 U.S.C. § 1395w-102(e)(1). These two requirements are not alternative tests for coverage. Rather, a medication must satisfy both requirements – i.e., it must be both "reasonable and necessary" and prescribed for a "medically accepted indication" – in order to require coverage under Part D. *See, e.g., Kilmer v.*

[6] Plaintiffs' brief – which was filed after the Court issued a show cause order because Plaintiffs failed to file the brief within the required period of time – contains no citation to the record or to any statute or regulation. The arguments, captioned "ultimate issues," contain only minimal analysis and the bulk of the brief is devoted to quoting from the opinion letter of a pharmacist, which is apparently not included in the record. (Doc. No. 15.) Plaintiffs' counsel is cautioned that, in the future, such a dearth of analysis or attempt at argumentation could result in this Court deeming his arguments waived. *See Rice v. Comm'r of Soc. Sec.*, 169 F. App'x 452, 454 (6th Cir.2006) ("It is well-established that 'issues averted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.'") (quoting *McPherson v. Kelsey*, 125 F.3d 989, 995–996 (6th Cir.1997)).

Leavitt, 609 F. Supp. 2d 750, 751 (S.D. Ohio 2009) ("A Part D plan sponsor need not provide coverage for a Part D drug that is not reasonable and necessary for circumstances specified in the statutory framework or that is not prescribed in accordance with the plan or the Medicare Act."). Accordingly, although the Appeals Council did not disturb the ALJ's conclusion that Actiq was reasonable and necessary to treat Mrs. Diamond's pain, that conclusion alone is not sufficient to merit coverage under Part D. This argument presents no basis for reversing the Secretary's final decision in this case.

2. MIPPA

Plaintiffs also argue that Mrs. Diamond satisfies the two-prong test of the MIPPA and, thus, she is entitled to coverage for the OTFC. Although not explicitly cited in their brief, Plaintiffs are apparently referring to former 42 U.S.C. § 1395w-104(b)(3)(G). That statute governed the contents of the formularies developed by Part D providers. It required part D providers to identify, and include in their formularies, categories or classes of drugs that satisfied two criteria, where: (1) restricted access to the medications would have "major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class"; and (2) there was a "significant clinical need" for access to drugs within those categories or classes. 42 U.S.C. § 1395w-104(b)(3)(G) (2009).

Plaintiffs' reliance on former § 1395w-104(b)(3)(G) is misplaced. As a preliminary matter, the two-prong test set forth in subsection(b)(3)(G) was eliminated by the Affordable Care Act. *See* Pub. L. No. 111-148, § 3307, 124 Stat. 119, 471-72 (2010) (amending subsection (b)(3)(G) to require the Secretary to "identify, as

appropriate, categories and classes of drugs . . . which the Secretary determines are of clinical concern"). The amendment applied "to plan year 2011 and all subsequent plan years." *Id*. Mrs. Diamond did not seek coverage from United Healthcare until January 2013. (Tr. 894.) Further, Plaintiffs do not explain why former subsection (b)(3)(G) applies in the context of determining whether the use of a particular medication qualifies for coverage as a Part D drug. They point to no authority applying the test in subsection (b)(3)(G) in any context other than requiring Part D providers to include certain categories or classes of drugs in their formularies. Accordingly, this argument presents no basis for reversing the Secretary's final decision in this case.[7]

3. Exception for Rare Diseases

Finally, Plaintiffs argue that, because there has been insufficient research into the use of OTFC to treat pain caused by OPMD, the Secretary "is not privileged to defend his/her position on the basis that the subject medication does not meet the definition of 'medically acceptable indication.'" (Doc. No. 15 at 3.) Plaintiffs insist that, given the dearth of studies relevant to the use of Actiq to treat OPMD pain, Mrs.

---

[7] The opinion letter authored by a pharmacist that accompanies Plaintiffs' brief opines that Mrs. Diamond's use of Actiq satisfies the two-prong test of subsection (b)(3)(G). (Doc. No. 15-1.) The Secretary argues that this Court is prohibited from reviewing the letter because it is not included in the record of proceedings. The legal authority on which the Secretary relies, however, applies in the context of a court's substantial evidence review where a plaintiff relies on evidence submitted to the Appeals Council after an ALJ decision. *See Foster v. Halter*, 279 F.3d 348, 357 (6th Cir. 2001) ("[T]his Court has repeatedly held that evidence submitted to the Appeals Council after the ALJ's decision cannot be considered part of the record for purposes of substantial evidence review."). Here, Plaintiffs rely on the pharmacist's letter to argue that the use of Actiq in this case satisfied the requirements of subsection (b)(3)(G). The two-prong test of former subsection (b)(3)(G) does not apply in this context, however, and, thus, the Court need not determine whether it is appropriate to consider the pharmacist's letter.

Diamond is entitled to rely on a different test – specifically the test set forth in former subsection (b)(3)(G) – to demonstrate that the medication was prescribed for a "medically acceptable indication." (*Id.*) Plaintiffs, however, point to no legal authority that permits the Court to create such an exception to the relevant statutory requirements. Indeed, Plaintiffs offer nothing more than the conclusory assertion that Mrs. Diamond is entitled to rely on an alternative test because her condition is rare. At least one other court has rejected a similar argument – more thoroughly developed than the general assertion put forth by Plaintiffs in this case – that a dearth of research into a particular indication for a medication requires the application of a different standard for determining whether the medication qualifies as a "covered part D drug." *See, e.g.,* *Kilmer v. Leavitt*, 609 F. Supp. 2d 750, 756 (S.D. Ohio 2009) (applying a *Chevron* analysis and rejecting the plaintiff's argument that coverage applies where an off-label use is medically necessary). Accordingly, this argument presents no basis for reversing the Secretary's final decision in this case.

III. CONCLUSION

For the foregoing reasons, the Magistrate Judge recommends that: (1) the claims of Mr. Diamond be DISMISSED for lack of jurisdiction; and (2) the Secretary's final decision be AFFIRMED.

s/ *Nancy A. Vecchiarelli*
U.S. Magistrate Judge

Date: January 6, 2015

OBJECTIONS

Any objections to this Report and Recommendation must be filed with the Clerk of Court within fourteen (14) days after the party objecting has been served with a copy of this Report and Recommendation. 28 U.S.C. § 636(b)(1). Failure to file objections within the specified time may waive the right to appeal the District Court's order. *See United States v. Walters*, 638 F.2d 947 (6th Cir. 1981); *Thomas v. Arn*, 474 U.S. 140 (1985), *reh'g denied*, 474 U.S. 1111 (1986).